IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE REGENERON PHARMACEUTICALS, INC.	**MISCELLANEOUS ACTION** **NO. 24-49-KSM**

MEMORANDUM

Marston, J. **September 6, 2024**

Regeneron Pharmaceuticals, Inc. ("Regeneron") filed the instant ex parte application pursuant to 28 U.S.C. § 1782 seeking leave to serve two subpoenas on Sharp Packaging Services, LLC ("Sharp"), who is a relevant third-party to a pending patent infringement lawsuit Regeneron brought against Samsung Bioepis Co., Ltd., and Samsung Biologics Co., Ltd. in South Korea (together "Samsung"). (Doc. No. 1.) For the reasons set forth below, the Court will grant this application and provide Regeneron leave to serve these two subpoenas on Sharp.

I. BACKGROUND

Regeneron is a biotechnology company that "engages in the business of researching/developing and manufacturing/distributing drugs [and] active pharmaceutical ingredients." (Doc. No. 1-14 at 39.) One of Regeneron's pharmaceutical products is EYLEA, a drug used to treat "macular degeneration, macular edema, diabetic retinopathy, retinopathy of prematurity, and macular edema following retinal vein occlusion." (Doc. No. 1-3 at 6.) As is relevant for purposes of the instant application, Regeneron maintains three South Korean patents related to EYLEA and its active ingredient, aflibercept:

- Patent No. 10-0659477 (the "477 Patent") which relates to aflibercept and expired on January 9, 2024;
- Patent No. 10-1406811 (the "811 Patent"), a formulation patent

that relates to the specific formulation contained in EYLEA, and which expires on June 14, 2027;[1] and

- Patent No. 10-2519234 (the "234 Patent"), a manufacturing patent that provides a method for preparing aflibercept for commercial use using chromatography, and which expires on August 18, 2040.

(Doc. No. 1-3 at 6.)

In 2012, Samsung Biologics established Samsung Bioepis, a joint venture with Biogen, Inc. used to develop, manufacture, and market certain biosimilar medicines.[2] (*Id.*) One of this joint venture's products, SB15, is purportedly biosimilar to Regeneron's EYLEA and contains the same active ingredient, aflibercept. (*Id*; Doc. No. 1-6 at ¶ 7.) SB15 is currently approved by regulatory authorities in South Korea, the United States, and Japan, and Samsung is seeking approval in other jurisdictions. (Doc. No. 1-3 at 6.) Samsung is responsible for making the drug substance, which is then formulated into the drug product. (*Id.* at 7.) The drug product is then sent to manufacturers, who are responsible for assembling, labeling, and/or packaging the product into vials and prefilled syringes. (*Id.*) Sharp Packaging Services, LLC, a limited liability company with a principal place of business in Allentown, Pennsylvania, is one such manufacturer of SB15. (*Id.*; Doc. No. 1-6 at ¶ 10; Doc. No. 1 at ¶ 3.) It is a wholly owned subsidiary of Sharp Services LLC, which similarly has its principal place of business in Allentown, Pennsylvania. (Doc. No. 1 at ¶ 3.) Along with assisting in the assembly of the

[1] Regeneron's complaint in the South Korean litigation suggests that Samsung is challenging the validity of Regeneron's 811 Patent in multiple countries. (Doc. No. 1-14 at 49.) The Court does not know if or how this matter has resolved.

[2] According to Regeneron in the underlying patent litigation, "'[b]iosimilar' refers to a biopharmaceutical for which the quality and clinically/non-clinically comparability have been confirmed in reference to a drug which has already obtained a regulatory approval for manufacture/marketing and import." (Doc. No. 1-14 at 40 n.4.)

SB15, Regeneron believes that Sharp may be involved in "the storage, stockpiling and shipping of commercial scale quantities of SB15 drug product for commercialization," given its "cold chain storage and specialty distribution capabilities." (Doc. No. 1-6 at ¶ 11.)

On January 16, 2023, Regeneron filed a patent infringement suit against Samsung Biologics and Samsung Bioepis in the Seoul Central District Court of South Korea, alleging that they infringed upon the 477 Patent. (Doc. No. 1-13.) In particular, Regeneron asserted that Samsung was "practicing the [477 Patent] at a level beyond what is necessary for research or testing for marketing approval" and that it was "it is highly likely that [Samsung] will produce [Samsung's] Products in Korea in order to sell the product in a foreign country before January 2024 when the [477] Patent expires." (*Id.* at 24.) Then, on May 14, 2024, Regeneron[3] filed a second patent infringement suit in the same court against Samsung Biologics, Samsung Bioepis, and Sam-Il Pharmaceuticals Co., Ltd.,[4] alleging that they infringed upon the 811 and 234 Patents. (Doc. No. 1-14.) Regeneron alleged that the defendants violated the 811 Patent by utilizing a formulation that is "substantially identical" to EYLEA and that the content of the defendant's biosimilar product makes it "very likely" that they used the manufacturing process embodied in the 234 Patent. (*Id.* at 53–54.)

On August 23, 2024, Regeneron filed the instant application, seeking leave to serve two subpoenas on Sharp. (Doc. No. 1.) The first subpoena requests that Sharp produce certain

[3] The Complaint in the second matter also lists Bayer Consumer Care AG, who is the exclusive licensee of the patents at issue, as a plaintiff. (Doc. No. 1-14 at 39.)

[4] Sam-Il Pharmaceuticals Co., Ltd. was not named as a defendant in the initial infringement suit regarding the 477 Patent. Regeneron describes the relationship between the three entities as follows: "Defendants' Product is manufactured in Korea by [Samsung Biologics], exported to the U.S. where it goes through packaging procedures etc., re-imported back into Korea by [Samsung Bioepis], and then sold by [Sam-Il Pharmaceuticals]." (Doc. No. 1-14 at 40.)

documents generally related to its manufacturing relationship with Samsung and the second requests deposition testimony from a Sharp corporate representative. (Doc. Nos. 1-1, 1-2.) In support of its application, Regeneron also submits two affidavits: one from Seong-Soo Park, who served as a judge for 16 years in the Suwon District Court, the Seoul Central District Court, the Daejeon District Court, and the Korean Patent Court (Doc. No. 1-5), and one from Duck Soon Chang, an attorney representing Regeneron in the South Korean proceedings (Doc. No. 1-6).

II. ANALYSIS

Regeneron files its ex parte application[5] pursuant to 28 U.S.C. § 1782, which provides, in relevant part:

> The district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal, including criminal investigations conducted before formal accusation. The order may be made . . . upon the application of any interested person and may direct that the testimony or statement be given, or the document or other thing be produced, before a person appointed by the court. . . . To the extent that the order does not prescribe otherwise, the testimony or statement shall be taken, and the document or other thing produced, in accordance with the Federal Rules of Civil Procedure.
>
> A person may not be compelled to give his testimony or statement

[5] As numerous other courts in this circuit have held, it is appropriate for parties seeking relief under § 1782 to file their application ex parte and for the Court to rule on the application ex parte. *See, e.g.*, *In re Ex Parte Application of Societe d'Etude de Realisation et d'Exploitation Pour le Traitement du Mais*, No. 13-MC-0266, 2013 WL 6164435, at *2 n.1 (E.D. Pa. Nov. 22, 2013) ("Any fair interpretation of § 1782(a)'s plain language . . . especially when made in conjunction with the purposes of the statute as discussed by the Supreme Court in *Intel*, should read it to encompass ex parte proceedings."); *In re Mesa Power Grp. LLC*, No. 2:11-mc-280-ES, 2012 WL 6060941, at *4 (D.N.J. Nov. 20, 2012) ("[I]t is appropriate for this Court to issue the order [granting the Section 1782 application] on an ex parte basis, without prejudice to the rights of the subpoenaed parties to file a motion to vacate or quash within thirty days of the issuance of this order." (quotation marks omitted)); *see also In re Sungrove Co., Ltd.,* No. 23-MC-80080-BLF, 2023 WL 2699987, at *2 (N.D. Cal. Mar. 28, 2023) ("Section 1782 applications are generally considered on an ex parte basis because parties will be given adequate notice of any discovery taken pursuant to the request and will then have the opportunity to move to quash the discovery or to participate in it." (quotation marks omitted)).

> or to produce a document or other thing in violation of any legally applicable privilege.

28 U.S.C. § 1782(a). The purpose of this provision is "to provide federal-court assistance in gathering evidence for use in foreign tribunals." *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 247 (2004); *In re Bayer AG*, 146 F.3d 188, 191–92 (3d Cir. 1998) ("[Section] 1782 was designed to facilitate the conduct of litigation in foreign tribunals, improve international cooperation in litigation, and put the United States into the leadership position among world nations in this respect."). When ruling on an application made pursuant to § 1782, the Court must first ensure that the mandatory requirements set forth in the statute are met. *SPS Corp I, Fundo de Investimento em Direitos Creditorios Nao Padronizados v. Gen. Motors Co.*, 110 F.4th 586, 590–91 (3d Cir. 2024). These statutory requirements consist of the following: (1) the person from whom discovery is sought "resides or is found" within the district; (2) the discovery is "for use in a proceeding in a foreign or international tribunal"; and (3) the application is made by an "interested person." *Id.* Then, the Court must determine whether discretionary factors set forth by the Supreme Court in *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241 (2004) weigh in favor of granting relief. *See SPS Corp I, Fundo de Investimento em Direitos Creditorios Nao Padronizados*, 110 F.4th at 591; *Intel*, 542 U.S. at 255 ("The statute authorizes, but does not require, a federal district court to provide assistance to a complainant. . . ."). These discretionary factors include the following: (1) whether "the person from whom discovery is sought is a participant in the foreign proceeding"; (2) "the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance"; (3) "whether the § 1782(a) request conceals an attempt to circumvent foreign proof gathering restrictions or other policies of a foreign country or the United States"; and (4) whether the

request is "unduly intrusive or burdensome." *Intel*, 542 U.S. at 264–65.

In determining whether to grant relief under § 1782, the Court keeps in mind the statute's "twin aims" of "providing efficient assistance to participants in international litigation and encouraging foreign countries by example to provide similar assistance to our courts." *In re Biomet Orthopaedics Switzerland GmBh*, 742 F. App'x 690, 696 (3d Cir. 2018) (quoting *Intel*, 542 U.S. at 252); *In re Chevron Corp.*, 633 F.3d 153, 161 (3d Cir. 2011) ("The Supreme Court cautioned . . . that 'comity and parity concerns may be important as touchstones for a district court's exercise of discretion in particular cases.'" (alterations accepted)). The Court also recognizes that "[s]ection 1782 is to be interpreted liberally." *In re Iraq Telecom Ltd.*, No. MC 19-175, 2023 WL 2402873, at *3 (E.D. Pa. Mar. 8, 2023). With these principles in mind, the Court considers each set of factors in turn below.

As an initial matter, the Court finds that the statutory requirements under § 1782 are satisfied. First, the record before the Court indicates that Sharp has multiple locations in Allentown, Pennsylvania (Doc. No. 1-9), including the location in which it manufactures SB15, (Doc. No. 1-6 at ¶ 10 ("Samsung's South Korean product approval report for SB15 identifies Sharp's Allentown location with respect to manufacture of SB15"), and may very well maintain its principal place of business in Allentown (Doc. No. 1 at ¶ 3). Additionally, according to Regeneron, Sharp Packaging Services, LLC is a wholly owned subsidiary of Sharp Services LLC, which also has its principal place of business in Allentown, Pennsylvania. (Doc. No. 1 at ¶ 3.) Thus, it appears that Sharp is "found" and or "resides" in the Eastern District of Pennsylvania. *See In re Sungrove Co., Ltd.*, 2023 WL 2699987, at *2 (holding that an LLC was "found" in the Northern District of California because it was headquartered in San Francisco); *In re Ex Parte Application of Societe d'Etude de Realisation et d'Exploitation Pour le Traitement*

du Mais, 2013 WL 6164435, at *2 (finding the first factor satisfied where the party from whom discovery was sought had an address in Chesterbrook, Pennsylvania). Second, the discovery sought is for use in a foreign proceeding, namely the two patent infringement lawsuits Regeneron has filed against Samsung in the South Korean court system. *See In re Regeneron Pharms., Inc.*, No. 23-mc-248-MN-LDH, Doc. No. 23, at 4 (D. Del. July 12, 2023) ("[T]he discovery sought is sought for use in proceedings before the South Korean courts and the South Korean patent office, which are 'foreign or international tribunals.'" (alterations accepted)). And finally, Regeneron, as the plaintiff in the South Korean litigation, is a "quintessential interested party." *SPS Corp I, Fundo de Investimento em Direitos Creditorios Nao Padronizados*, 110 F.4th at 591; *see also Intel*, 542 U.S. at 256 ("No doubt litigants are included among, and may be the most common example of, the 'interested person[s]' who may invoke § 1782."). Thus, the Court finds the mandatory statutory requirements satisfied and turns to whether the *Intel* factors weigh in favor of the Court granting Regeneron's application.

The first *Intel* factor requires the Court to consider whether "the person from whom discovery is sought is a participant in the foreign proceeding." 542 U.S. at 264. "Resort to Section 1782 is disfavored when the targets of discovery are actual participants in the foreign proceeding," *In re JSC United Chem. Co. Uralchem*, No. CV 20-3651 (CCC), 2020 WL 4251476, at *6 (D.N.J. July 24, 2020), because "[a] foreign tribunal has jurisdiction over those appearing before it, and can itself order them to produce evidence," *Intel* 542 U.S. at 264. On the other hand, when the person from whom discovery is sought is *not* a participant, the need for aid under § 1782 is generally more apparent. *Id*. "Nonparticipants in the foreign proceeding may be outside the foreign tribunal's jurisdictional reach; hence, their evidence, available in the United States, may be unobtainable absent § 1782(a) aid." *Id.* Here, Sharp is not a party to the

South Korean patent litigation and appears to be outside of the jurisdictional reach of the South Korean court. *See* (Doc. No. 1-6 at ¶ 19 (Chang Decl.) ("Sharp is not a party to the South Korean Proceedings, and there is no mechanism under South Korean law for the South Korean Court directly to obtain third-party discovery located in the United States. The South Korean Court does not have jurisdiction over Sharp and therefore lacks authority to compel Sharp to produce the requested discovery."); Doc. No. 1-5 at ¶ 7 (Park Decl.) ("[T]here is no mechanism under South Korean law by which a South Korean court may issue a document production order to a non-party U.S. company located outside of South Korea, like Sharp.").) Thus, the Court finds that the first *Intel* factor favors granting the application. *See In re Chevron Corp.*, 633 F.3d at 162 ("The first Intel factor favors allowing Chevron to obtain the discovery it seeks because UBR is not a participant in the Lago Agrio litigation and, so far as we can determine from the record before us, is not subject to the jurisdiction of the Lago Agrio Court."); *In re Regeneron Pharms., Inc.*, No. 23-mc-248-MN-LDH, Doc. No. 23, at 5 (D. Del. July 12, 2023) ("Because Biogen is not a party to the South Korean proceedings, I find that this factor weighs in favor of Regeneron' s § 1782 application.").

The second *Intel* factor requires the Court to consider "the receptivity of the foreign government or the court or agency abroad to U.S. federal court judicial assistance." 542 U.S. at 264. In analyzing this factor, the Court does not consider whether the particular evidence sought would ultimately be admissible in the South Korean court. *See In re Biomet Orthopaedics Switzerland GmBh*, 742 F. App'x at 697 ("Surveying German law to determine a particular document's admissibility or probative value is exactly the kind of speculative foray into legal territories unfamiliar to federal judges, that would be in tension with § 1782." (quotation marks omitted and alterations accepted)). Instead, the Court need only consider whether South Korean

courts are *generally* receptive to evidence obtained from foreign courts. *See id.* at 698; *In re Regeneron Pharms., Inc.*, No. 23-mc-248-MN-LDH, Doc. No. 23, at 6 (D. Del. July 12, 2023) ("[The Court] need only determine whether Biogen has satisfied its burden to show that the South Korean court would not be receptive to this Court's judicial assistance.").

Here, Regeneron has put forth convincing evidence that South Korean courts are accepting of the § 1782 process. Regeneron has submitted two affidavits from South Korean practitioners, including Seong-Soo Park, who served as a judge in the South Korean court system for 16 years, providing that South Korean courts are receptive to materials received through § 1782(a) requests. (Doc. 1-5 at ¶¶ 2, 13 (Park Decl.) ("[I]t is my opinion that discovery obtained in official proceedings before foreign courts, such as proceedings under Section 1782 will be evaluated and considered the same as other evidence submitted in legal proceedings in South Korea. This is the case for both documents and testimony."); Doc. No. 1-6 (Chang. Decl.) at ¶¶ 22–23 ("It is also my opinion that the South Korean Court would consider the evidence that Regeneron seeks to obtain through its application. The approach to foreign discovery under South Korean law is liberal, and South Korean courts consider evidence obtained abroad.").) Indeed, as Regeneron points out, South Korean courts themselves have utilized § 1782 in the past. (Doc. No. 1-3 at 13–14; Doc. No. 1-6 at ¶ 24); *see In re Request for Jud. Assistance from Seoul Cent. Dist. Court*, No. 23-mc-80016-BLF, 2023 WL 2394545, at *4 (N.D. Cal. Mar. 7, 2023); *In re Request for Int'l Jud. Assistance From the Nat'l Ct. Admin. of the Republic of Korea*, No. C15-80069 MISC LB, 2015 WL 1064790, at *1 (N.D. Cal. Mar. 11, 2015). Unsurprisingly then, numerous other courts have found that South Korean courts are receptive to discovery obtained through the aid of United States federal courts. *See, e.g.*, *In re Woori Bank*, No. 21-mc-80084-DMR, 2021 WL 2645812, at *3–4 (N.D. Cal. June 28, 2021) (granting Section

1782 application seeking discovery for use in litigation before the Seoul Central District Court); *In re Medytox, Inc.*, No. 18-mc-00046-TWP-DLP, 2019 WL 3162174, at *10 (S.D. Ind. July 16, 2019) (same); *In re Regeneron Pharms., Inc.*, No. 23-mc-248-MN-LDH, Doc. No. 23, at 10 (D. Del. July 12, 2023) (same). The Court thus finds that the second factor weighs in favor of granting Regeneron's application.

The third *Intel* factor requires the Court to determine whether "the § 1782(a) request conceals an attempt to circumvent foreign proof gathering restrictions or other policies of a foreign country or the United States." 542 U.S. at 264–65. "A discovery request under § 1782 is viewed as an attempt to circumvent foreign proof-gathering restrictions when the foreign tribunal has already rejected requests for the same documents." *In re Regeneron Pharms., Inc.*, No. 23-mc-248-MN-LDH, Doc. No. 23, at 6 (D. Del. July 12, 2023); *see also In re Chevron Corp.*, 633 F.3d at 163 ("Without a definitive determination that the Lago Agrio Court has denied Chevron access to the same documents that Chevron seeks in its section 1782 discovery application . . . it cannot be said that Chevron's section 1782 application is 'an attempt to circumvent foreign proof-gathering restrictions.'"). Here, the Court has no reason to believe that Regeneron's request is an attempt to circumvent the discovery process available to them in South Korea or that the South Korean court has previously rejected Regeneron's attempt to receive these same materials and testimony.[6] Additionally, it does not appear that there are any restrictions under

[6] While discovery available under South Korean law is much more limited than under the Federal Rule of Civil Procedures (Doc. No. 1-5 at ¶¶ 8–12 (explaining that the Korean Civil Procedure Act "requires a considerable degree of specificity regarding the document requested to be submitted" and that "judges often do not grant even a single document production order in civil lawsuit cases and, in many cases, parties do not file a single document production order request in the first place"); Doc. No. 1-6 at ¶¶ 17–21), "there is no requirement that the material be discoverable in the foreign country for it to be discoverable pursuant to a section 1782 request in the United States" *In re Chevron Corp.*, 633 F.3d at 163. Nor is there an exhaustion requirement through which Regeneron would be obligated to first attempt to receive the discovery through South Korean procedures. *See In re O'Keefe*, 646 F. App'x 263, 268 (3d Cir. 2016) ("We have never held that an applicant must seek discovery relief in the foreign forum first.").

South Korean law preventing Regeneron from seeking and using discovery from Sharp. (Doc. No. 1-5 at ¶ 13.) Thus, the Court finds that this factor weighs in favor of granting the application.

Finally, the fourth *Intel* factor requires the Court to consider whether the request is "unduly intrusive or burdensome." 542 U.S. at 265. "[A]ssessment of the fourth factor is virtually identical to the familiar 'overly burdensome' analysis" under the Federal Rules of Civil Procedure, which means that courts permit "discovery that appears reasonably calculated to lead to the discovery of admissible evidence." *In re Glob. Energy Horizons Corp.*, 647 F. App'x 83, 86 (3d Cir. 2016) (alteration adopted and quotation marks omitted). Here, Regeneron asserts that their subpoenas seek documents and testimony regarding "the export, import, storage, stockpiling and shipping of SB15" and "the information about SB15 that Sharp provided to regulatory authorities." (Doc. No. 1-3 at 7–8.) They claim this evidence is relevant to "Samsung's infringement of the Korean Patents, Samsung's experimental use defense, and damages in the South Korean Proceedings." (*Id.* at 16.) They also assert that their requests are limited in nature, particularly through their inclusion of language requiring Sharp to only produce "sufficient" information to satisfy certain requests. (*Id.*) The Court's review of the proposed subpoenas, albeit with only a limited window into the South Korean litigation, suggests that this summary is accurate. And significantly, to the extent that Sharp has an objection to the propriety or scope of the subpoena, nothing in this memorandum or corresponding order would prevent them from moving to quash the subpoena, after first working through their issues in good faith with Regeneron. *See In re Mesa Power Grp. LLC*, No. 2:11-mc-280-ES, 2012 WL 6060941, at *4 (D.N.J. Nov. 20, 2012) ("[I]t is 'appropriate for this Court to issue the [Section 1782 application] on an ex parte basis, *without prejudice to the rights of the subpoenaed*."

(emphasis added)); *In Re Woori Bank*, 2021 WL 2645812, at *4 (noting that the court granting the § 1782 application did "not preclude Teamblind from contesting the subpoena"); *cf. In re Biomet Orthopaedics Switzerland GmBh*, 742 F. App'x at 699 ("[I]t was erroneous to turn down Biomet's discovery request flat without requiring Heraeus to negotiate with Biomet over cutting down the request." (alterations accepted and quotation marks omitted)). Thus, the Court finds, at this stage, that the fourth *Intel* factor weighs in favor of granting the application.

* * *

In sum, the Court finds that Regeneron's application satisfies the statutory requirements and that all four of the discretionary factors weigh in favor of granting the application. Thus, the Court grants Regeneron leave to serve the two subpoenas attached to its motion on Sharp.

III. CONCLUSION

For the reasons set forth above, the Court grants Regeneron's application. An appropriate order follows.